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I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	2000/0592
Date of Filing	21 July 2000
Applicant	ATROPOS LIMITED, an Irish Company of Earlsfort Centre, Hatch Street, Dublin 2, Ireland.

Dated this 18 day of July 2001.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

FORM NO. 1

000592

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

__X__ the grant of a patent under Part II of the Act

_____ the grant of a short-term patent under Part III of the Act on the basis of the information furnished hereunder.

1. Applicant(s)

Name ATROPOS LIMITED

Address 1 Earlsfort Centre
Hatch Street
Dublin 2
Ireland

Description/Nationality

An Irish Company

2. Title of Invention

"A Medical Device"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date	Country in or for which filed	Filing No.

4. Identification of Inventor(s)
Name(s) of person(s) believed
by Applicants(s) to be the inventor(s)

Name: Franciscus Laurents Moll, a Dutch citizen.
Address: Duinweg 21, NL-3735 LA Bosch en Duin, The Netherlands.

Name: Menno Kalmann, a Dutch citizen.
Address: Hellenkant 45, NL-8075 PD Elspeet, The Netherlands.

5. Statement of right to be granted a patent (Section 17(2) (b)

00592

The Applicant derives the rights to the Invention by virtue of a Deed of Assignment dated July 20, 2000.

6. Items accompanying this Request – tick as appropriate

(i)	X	Prescribed filing fee (£100.00)
(ii)	X	Specification containing a description and claims
	_____	Specification containing a description only
	_____	Drawings referred to in description or claims
(iii)	_____	An abstract
(iv)	_____	Copy of previous application (s) whose priority is claimed
(v)	_____	Translation of previous application whose priority is claimed
(vi)	X	Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant (s))

7. Divisional Application (s)

The following information is applicable to the present application which is made under Section 24 –

Earlier Application No: .....

Filing Date: .....

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

Name	Address
John A. O'Brien & Associates	The address recorded for the time being in the Register of Patent Agents, and currently Third Floor, Duncairn House, 14 Carysfort Avenue, Blackrock, Co. Dublin, Ireland.

9. Address for Service (if different from that at 8)

As above

Signed _____ JOHN A. O'BRIEN & ASSOCIATES

Date July 21, 2000

"A MEDICAL DEVICE"

Introduction

The invention relates to a stent device suitable for internally supporting vessels, in particular circular vessels in the medical and non-medical fields.

The collapse of vessels, such as transmission pipes, for example water and fuel pipes, is very problematical and in some circumstances can lead to dangerous consequences.

A serious medical problem is the silting up of blood vessels, for instance with calcium, this being called arteriosclerosis. This can lead to a blockage of the blood vessel, called stenosis. Stenosis of blood vessels can cause a complete blockage of the blood vessel which leads to serious health consequences, for example circulatory problems, for the sufferer, whereby a rapid deterioration in health ensues. Advanced stenosis if not operated upon can cause wastage and death of body tissue necessitating in certain cases, in amputation.

Inflatable, tubular prostheses, commonly referred to as stents, are known, which can be inserted into blocked tubular organs and subsequently expanded in order to re-open these organs. Stents are made from material alien to the body, it is often necessary to remove the stent once the acute situation has been treated. Otherwise there exists a very real danger of thromboses and infections resulting from bodily rejection of the stent material.

Statements of Invention

According to one aspect there is provided a method for preparing an expandable stent comprising the steps of:-

forming a generally spiral shaped element having a first free end and a second free end, the spiral element having a contracted configuration in which the first free end is an inner free end and the second free end is an outer free end; and

reversing the spiral so that the first free end becomes an outer free end and the stent is pretensioned.

In another aspect the invention provides a method for operating an expandable stent in the form of a generally spiral-shaped element the method comprising the steps of:-

delivering the stent in the pretensioned configuration to a desired site;

deploying the stent by expanding the stent to a first expanded configuration; and

retrieving the stent by expanding the stent further to a second expanded configuration.

In a further aspect the invention provides a method for manipulating a stent having a pretensioned contracted configuration, a first expanded configuration and a second expanded configuration, the method comprising the steps of:-

delivering the stent in a pretensioned contracted form to a desired site;

deploying the stent by expanding the stent to the first expanded configuration; and

subsequently retrieving the stent by further expanding the stent to the second expanded configuration whereby the stent collapses.

In one embodiment of the invention the pretensioned contracted stent is mounted on an introduction balloon catheter and the method includes the steps of advancing the balloon catheter to a desired site and inflating the introduction balloon to deploy the stent. Preferably the stent is retrieved by advancing a retrieval balloon catheter to the stent and inflating the retrieval balloon to expand the deployed stent to the second expanded configuration whereby the stent collapses.

The device according to the present invention can therefore be arranged between an expanded , locked arrangement wherein the vessel is itself expanded and held open, and the device can also be released from this expanded, locked, arrangement into a contracted arrangement wherein the device may be displaced into the vessel or removed therefrom simply by guiding it through the vessel concerned.

The stent can also be impregnated with, for example, a medicament, to act as a drug delivery system, whereby the drug can be very accurately dosed directly at the area to be treated, before being removed.

Furthermore, the stent can be re-usable. The stent may be provided with a medical tracer and/or radioactively "loaded" in order to provide accurate medical diagnosis, i.e. by means of imaging, and/or very accurate, localised radiation therapy.

The stent can be covered with a thin sheet/craft, i.e. a thin prosthesis for a blood vessel, urinary tract or such like. This sheet/craft can be elastically arranged around the stent. On expansion of the stent, the craft also expands whereby the

stent craft is displaced. On shrinkage of the stent, the sheet/craft also shrinks and can therefore be removed along with the stent. This can therefore be considered as a removable craft or a removable stent craft.

A non-elastic sheet/craft can also be arranged around the stent.

When the stent is then expanded, the sheet craft is again pushed against the wall of the lumen. However, on removal of the stent, this sheet craft remains behind.

This can be very important, for example in the following application:

A prosthetic for the inner wall of a blood vessel can be arranged thus. After a few days, the prosthetic has grown onto the blood vessel inner wall, whereby the stent is now superfluous. The stent is removed and the sheet craft remains behind.

Brief Description of Drawings

The invention will be more clearly understood from the following description thereof given by way of example only, in which:-

Fig. 1 is a perspective view of a stent in a first contracted configuration;

Fig. 2 is a perspective view of the stent of Fig. 1 in a pretensioned configuration;

Fig. 3 is a perspective view of the pretensioned stent loaded on an introducing balloon;

Figs. 4 to 6 are perspective views of the stent being deployed;

Fig. 7 is a perspective view of the deployed stent; and

Figs. 8 to 10 are perspective views of the stent being retrieved by a retrieval balloon.

Detailed Description

Referring to the drawings and initially to Fig. 1 thereof an expandable stent 1 is typically manufactured from a shape memory material such as Nitinol. The stent 1 comprises a series of rings 2, only two of which are illustrated. Each of the rings 2 is of generally spiral shape having a first free end 5 and a second free end 6. In the contracted configuration illustrated in Fig. 1 the first free end 5 is an inner free end and the second free end 6 is an outer free end. The first free end 5 is defined at the end of a strap portion 9 and a buckle portion 10 adjacent the second free end 6 has a first strap receiving slot 11 and a second strap receiving slot 12 which are most clearly visible in Figs. 8 and 9. The strap portion 9 is received in the slots 11, 12 to lock the stent in various configurations as described in more detail below.

To prepare the stent 1 for use, the spiral contracted configuration of Fig. 1 is reversed by pulling the inner free end 5 out over the outer free end 6 so that the first free end 5 becomes an outer free end and the second free end 6 becomes an inner free end as illustrated in Fig. 2 . The stent is thereby pretensioned and is urged to return to the contracted configuration of Fig. 1. In the pretensioned configuration of Fig. 2 the strap portion 9 extends outwardly through the slot 11 in the buckle portion 10.

The stent in the pretensioned configuration of Fig. 2 is then loaded onto an introduction balloon 20 of an introduction catheter 21. The catheter 21 is

advanced to a treatment site such as a stenosis. The introduction balloon 20 is inflated as illustrated in Figs. 4 and 5 until the free end 5 of the strap portion 9 is aligned with the slot 12. The strap portion 9 then engages in the slot 12 and is locked in this configuration by the engagement of a shoulder 25 adjacent to the strap section 9 against the stent wall in the region of the slot 12 as illustrated in Fig. 6. By this action the stent is locked in this first expanded configuration and the balloon 20 may be deflated and the introducer catheter 21 withdrawn leaving the stent in situ as illustrated in Fig. 7.

To retreive the stent 1 a retreiveal catheter 30 with a retrieval balloon 31 is advanced to the location of the stent. The retrieval balloon 31 is then inflated to expand to the diameter greater than that of the introducing balloon 20 causing the strap 9 to disengage from the slot 12 as illustrated in Fig. 8. Continued inflation of the retrieval balloon 31 pushes the slot 11 over the strap 9 until the free end 5 lies on the inside of the stent (Fig. 9). This is the manufactured configuration of the stent (Fig. 1) and on deflation of the retrieval balloon 31 the stent, by virtue of the shape memory of the material, contracts (Fig. 10). The contracted stent 1 is then removed from the vasculature carried by the retrieval balloon 31 on the retrieval catheter 30.

The invention is not limited to the embodiments hereinbefore described which may be varied in detail.

Claims

1. A method for preparing an expandable stent comprising the steps of:-

forming a generally spiral shaped element having a first free end and a second free end, the spiral element having a contracted configuration in which the first free end is an inner free end and the second free end is an outer free end; and

reversing the spiral so that the first free end becomes an outer free end and the stent is pretensioned.

2. A method for preparing a stent substantially as hereinbefore described with reference to the accompanying drawings.

3. A method for operating an expandable stent in the form of a generally spiral-shaped element the method comprising the steps of:-

delivering the stent in the pretensioned configuration to a desired site;

deploying the stent by expanding the stent to a first expanded configuration; and

retrieving the stent by expanding the stent further to a second expanded configuration.

4. A method for operating an expandable stent substantially as hereinbefore described with reference to the accompanying drawings.

5. A method for manipulating a stent having a pretensioned contracted configuration, a first expanded configuration and a second expanded configuration, the method comprising the steps of:-

delivering the stent in a pretensioned contracted form to a desired site;

deploying the stent by expanding the stent to the first expanded configuration; and

subsequently retrieving the stent by further expanding the stent to the second expanded configuration whereby the stent collapses.

6. A method as claimed in claim 5 wherein the pretensioned contracted stent is mounted on an introduction balloon catheter and the method includes the steps of advancing the balloon catheter to a desired site and inflating the introduction balloon to deploy the stent.

7. A method as claimed in claim 5 or 6 wherein the stent is retrieved by advancing a retrieval balloon catheter to the stent and inflating the retrieval balloon to expand the deployed stent to the second expanded configuration whereby the stent collapses.

8. A method for manipulating a stent substantially as hereinbefore described with reference to the accompanying drawings.

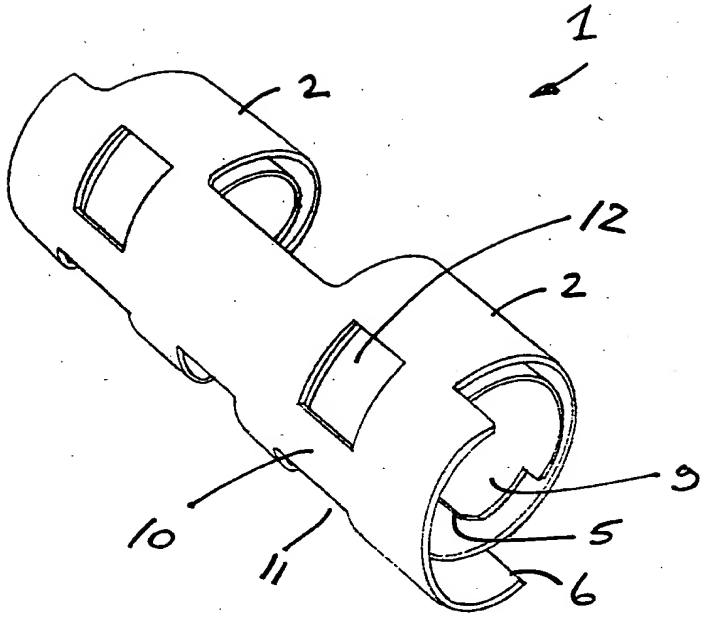

Fig. 1

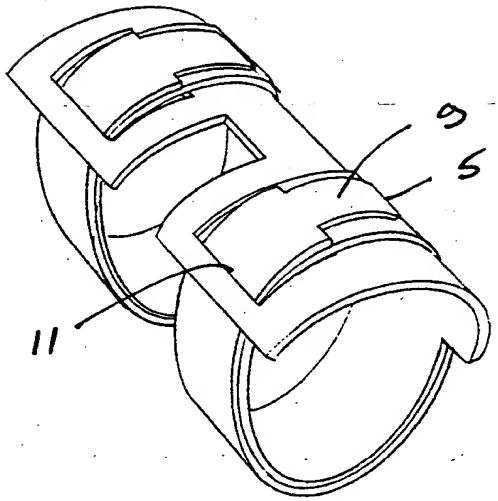

Fig. 2

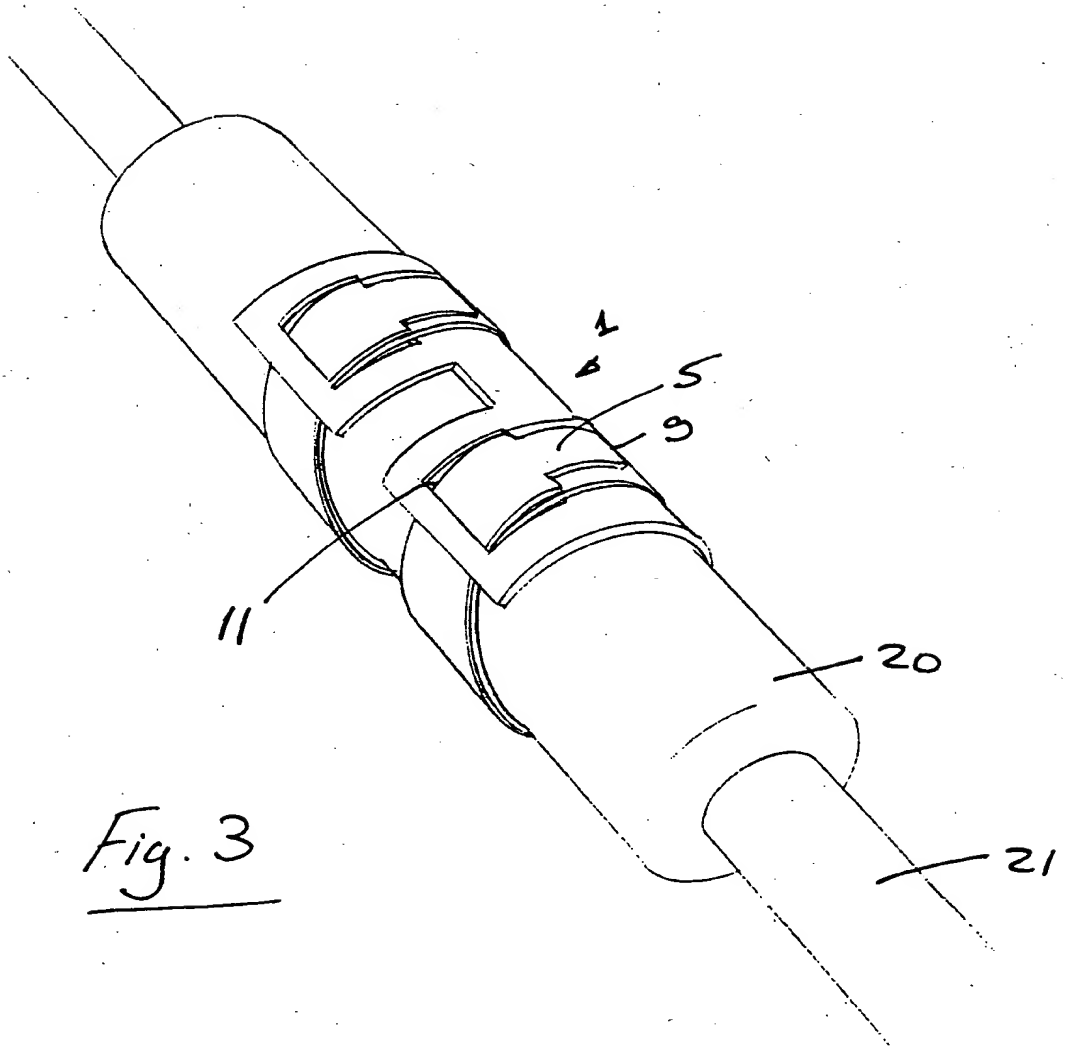

Fig. 3

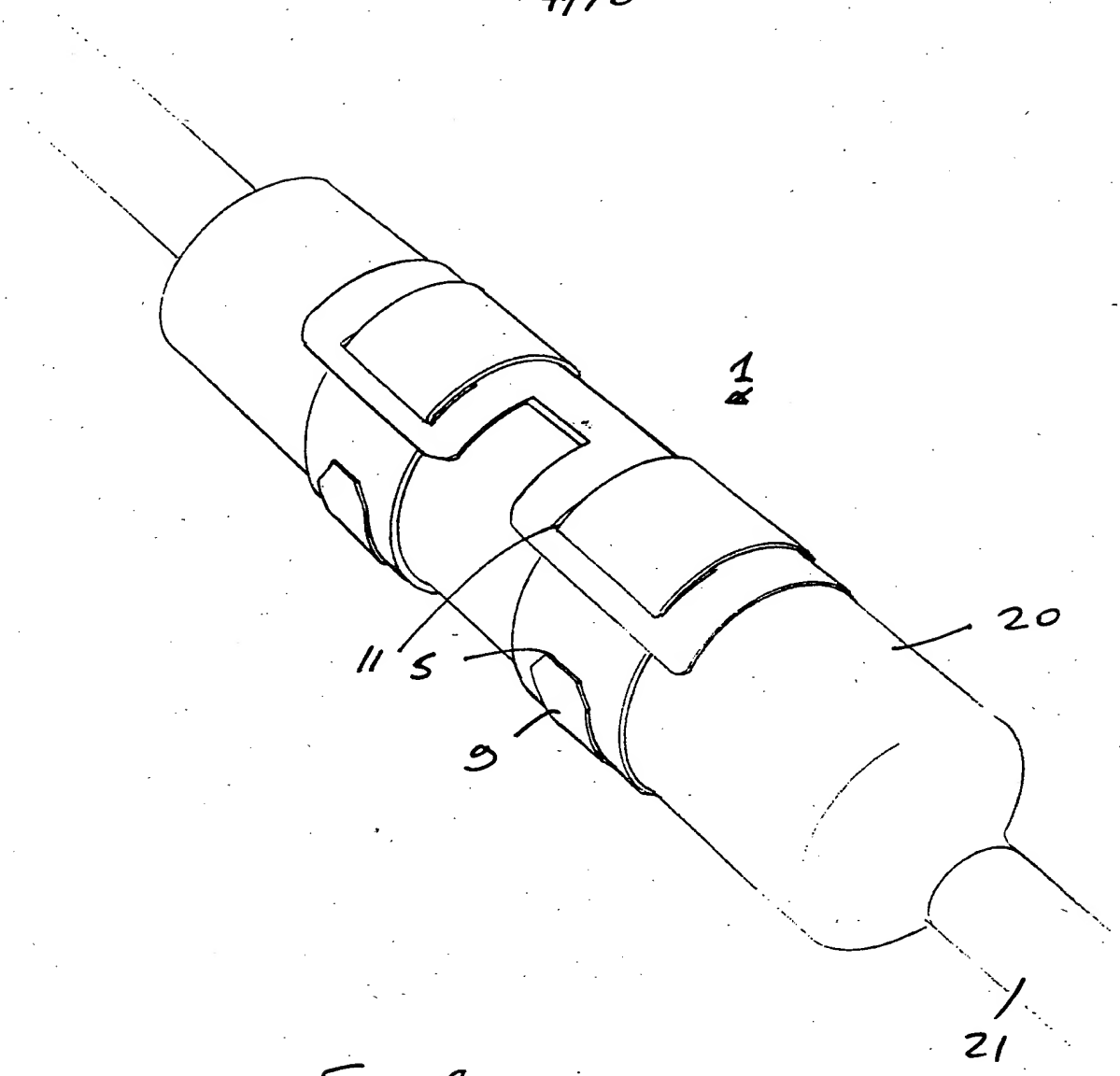

Fig. 4

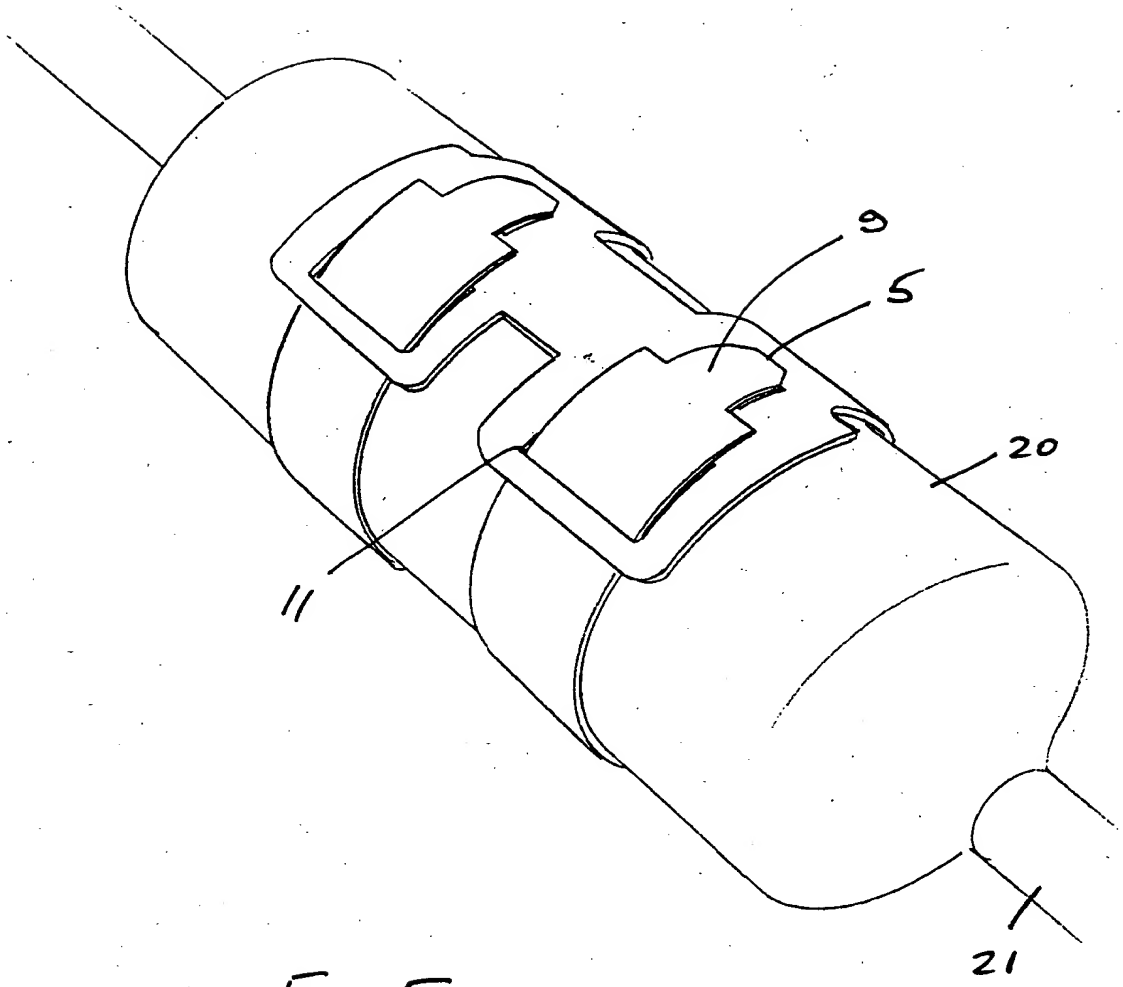

Fig. 5

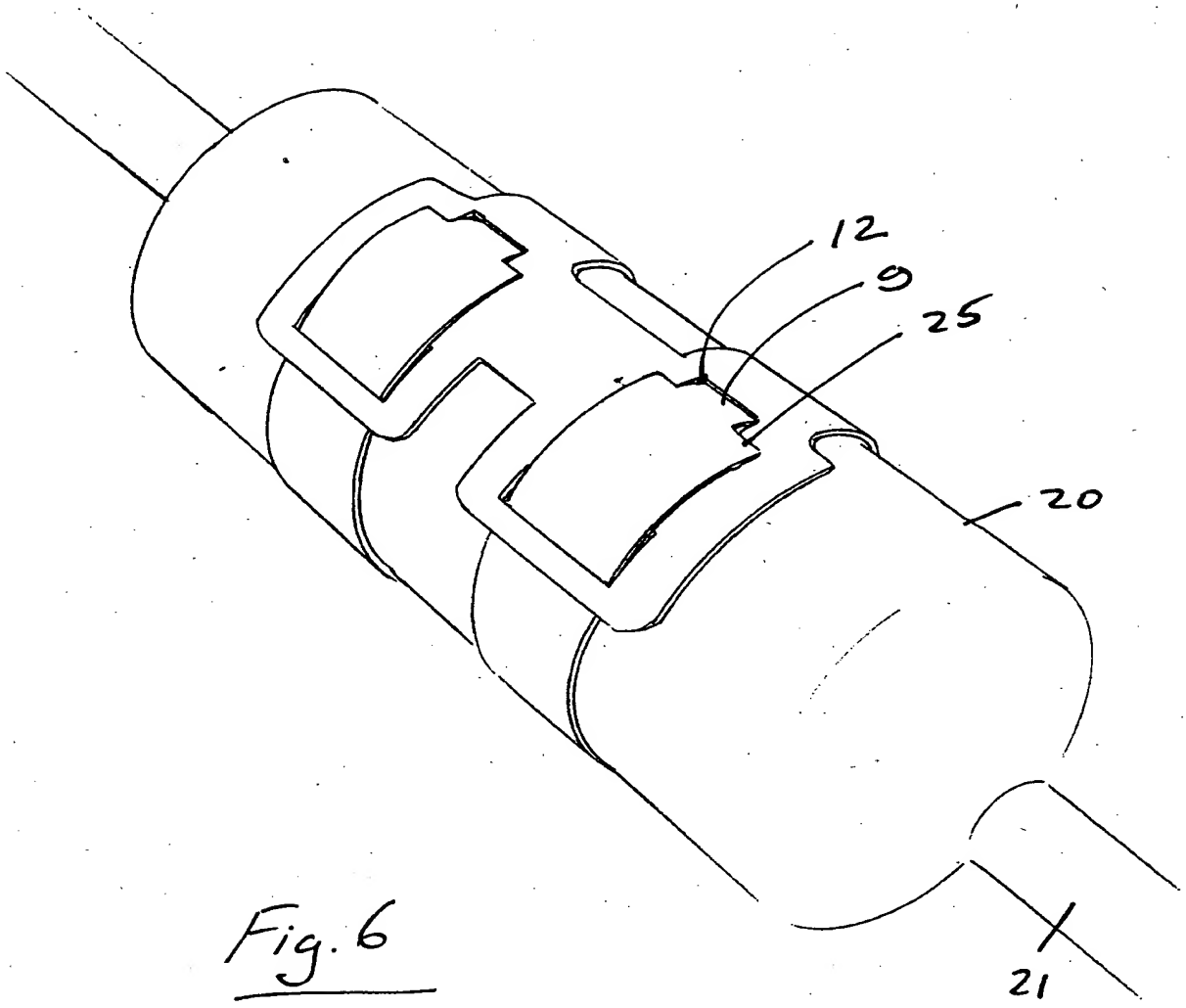

Fig. 6

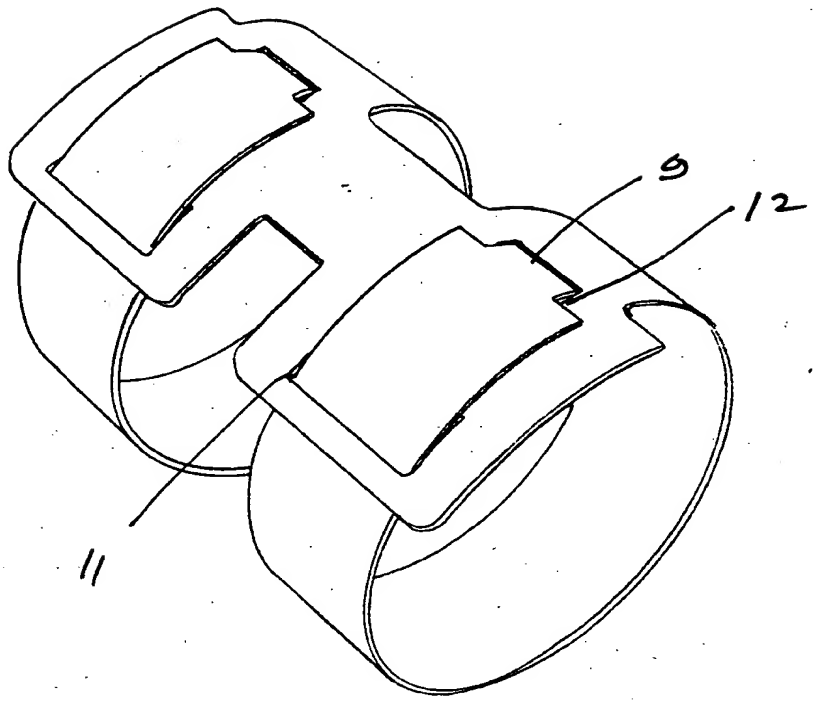

Fig. 7

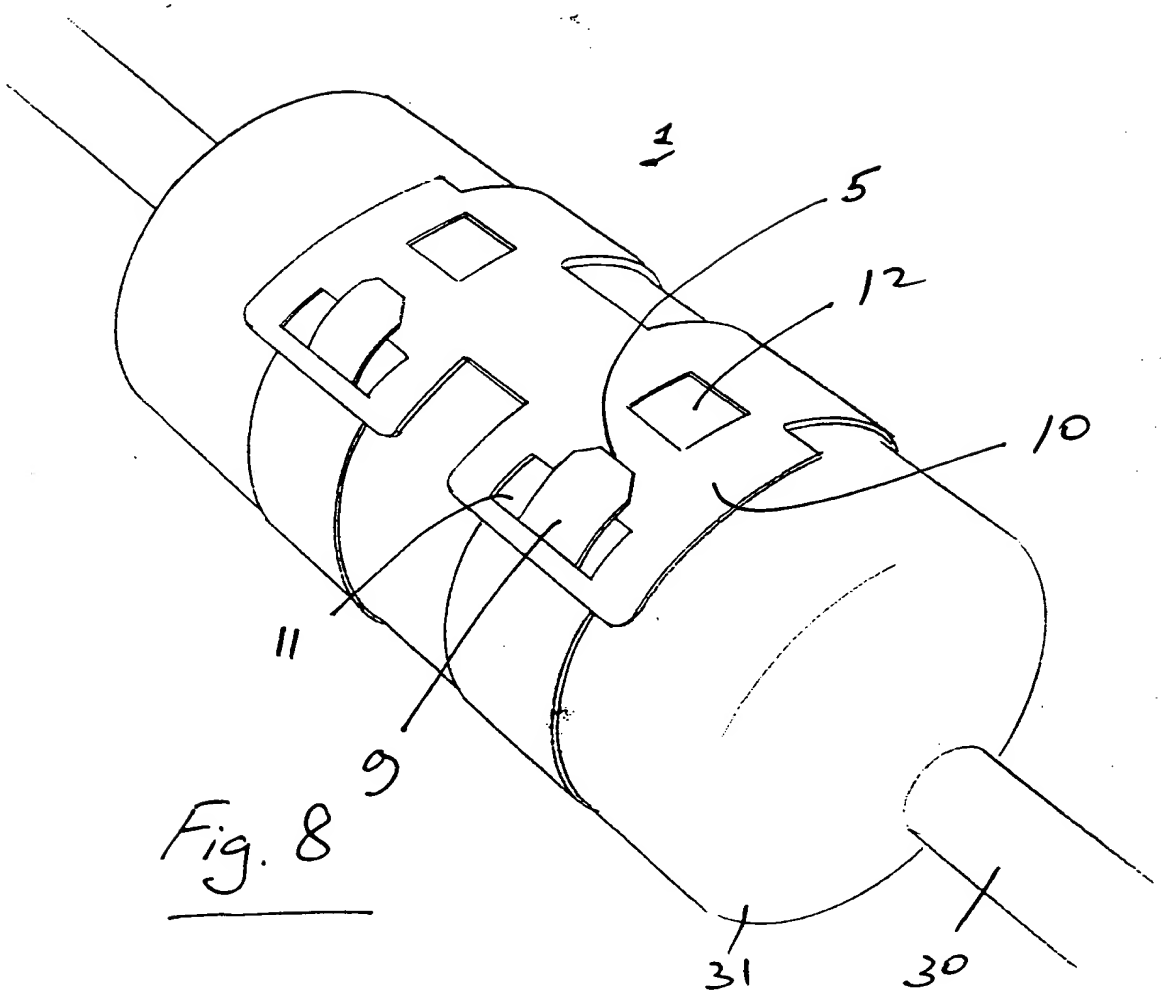

Fig. 8

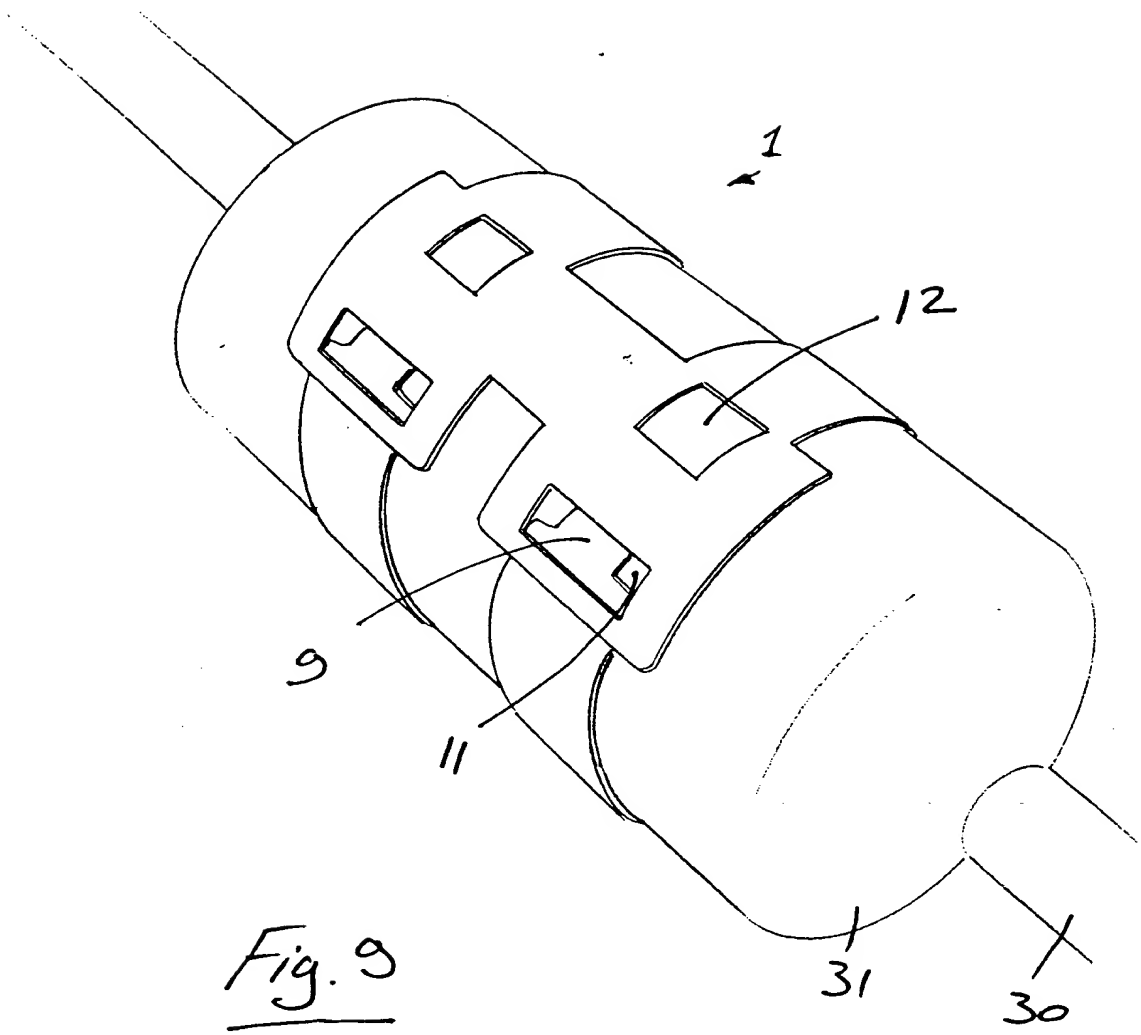

Fig. 9

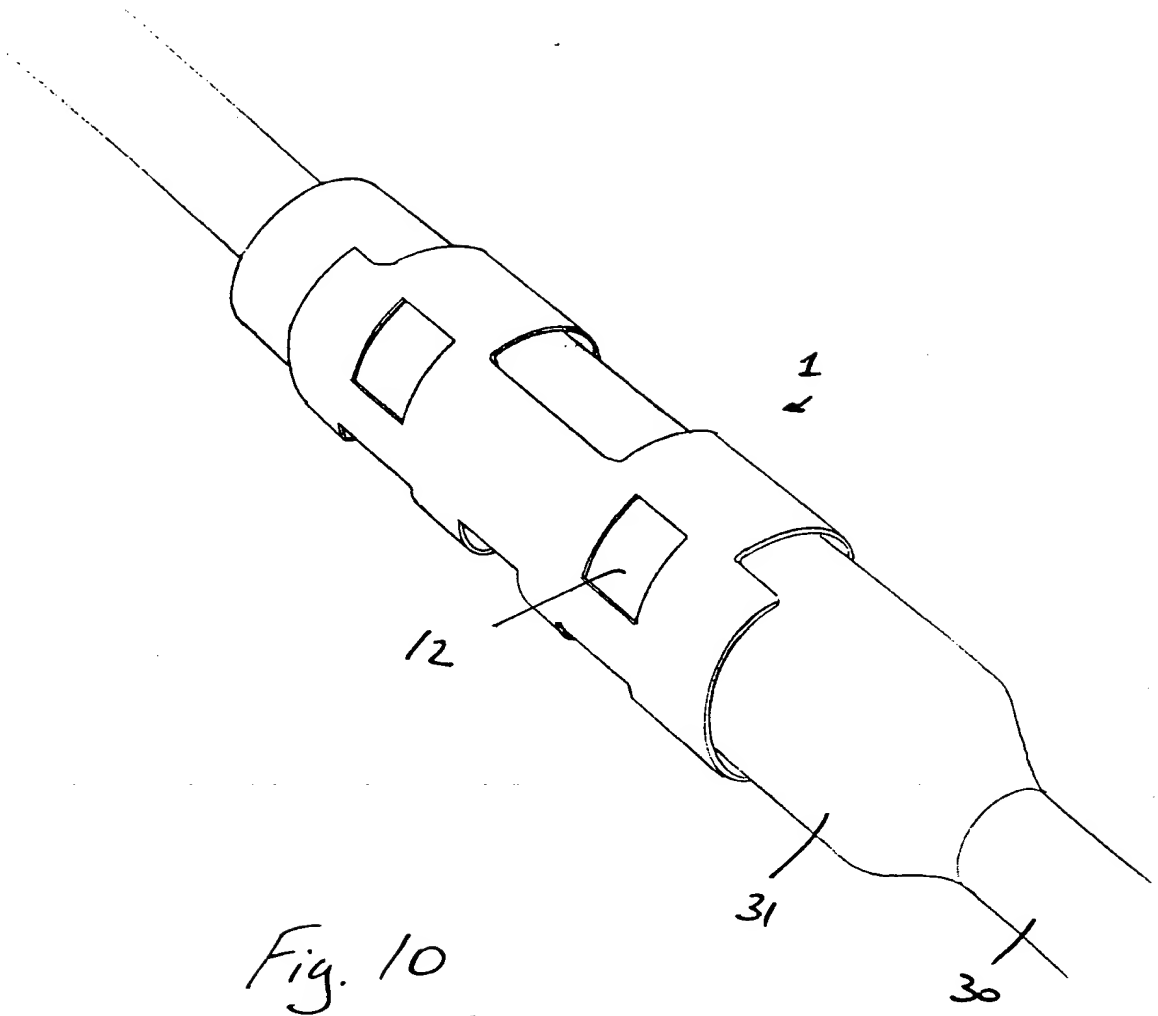

Fig. 10